MEMORANDUM

SUBJECT: Response to 30-day error-only comments on the Diclofop-methyl Red (Chemical # 110902, Case # 819442, Rereg Case # 2160 Bar Code # 267553)

FROM: F. Nicholas Mastrota
Environmental Risk Branch II
Environmental Fate and Effects Division 7507C

THRU: Tom Bailey, Chief
Environmental Risk Branch II
Environmental Fate and Effects Division 7507C

TO: Anne Overstreet
Reregistration Division (7505C)

This memo gives EFED response to the comments submitted by Aventis CropScience to the Agency on May 30, 2000 concerning the draft EFED RED chapter for diclofop-methyl. Below are summaries of Avantis's comments, followed by our responses.

1. *A conclusion of high reproductive risk to mammals is not warranted because the chronic risk assessment is unreasonably overprotective. The foliar half-life should be based on the data submitted indicating that the half-life is 0.42-1.25 days. Also, the initial maximum values from the Hoeger Kenaga nomogram were used.*

The default value of 30 days was used because EFED has not received sufficient information to support the claim that the foliar half-life of diclofop-methyl on wheat is 0.42 to 1.25. As explained in the footnote on page 9, a detailed study report would be needed to accept these results, not just a brief summary of the findings. EFED would need to assess the methodology of the study, how the samples were collected, and how the residues were analyzed to ascertain if the results are scientifically valid. Furthermore, since the data was not collected for the purpose of assessing exposure to wildlife, EFED would also need to assess how applicable these findings are to assessing exposure to wildlife under various field conditions. Without a complete review of this study, EFED cannot use the data for more than a discussion of uncertainty of the risk conclusion, which has been done.

The discussion of risk quotients for chronic risk to mammals (p. 35) describes the assessment as a "screen", indicating that the assessment was highly protective and should be used to determine if further refinement of the assessment is warranted. The chronic RQs exceeded the LOC of 1 by a factor of 8-11, indicating that there is a *potential* for being a high reproductive risk to mammals. It would be desirable to proceed to a more refined assessment, which would include a graph of the decline of maximum and mean foliar EEC's over time. However, such a refined assessment is not possible without acceptable data on foliar half-life of diclofop-methyl and its acid degredation product. As stated above, the summary data that was submitted is insufficient for use in this purpose. Therefore, EFED was compelled to leave the assessment at the screening level, and discuss the high level of uncertainty associated with the conclusion.

EFED acknowledges that the chronic risk to mammals is uncertain and would better be stated as a *potential* reproductive risk rather than a *high* reproductive risk. The wording of the RED has been revised accordingly on page 1 and pages 33-36.

2. *A fish bioaccumulation study (Guideline 165-4) and aquatic plant growth and reproduction study (Guidleine 123-2) should not be required for diclofop-methyl.*

Both of these studies are required. Although EPA has sufficient information from available studies to make preliminary qualitative assessment of the fate and effects of Diclofop Methyl, but they are insufficient to make a **complete assessment** on the fate and effects of Diclofop methyl and its degradates. Although diclofop rapidly degrades to diclofop acid, the bioaccumulation study submitted by the registrant could not be used for its intended purpose because it was not conducted using the valid protocol. The registrant needs to submit a valid bioaccumulation in fish (165-4) study for meeting the full requirements of Reregistration. Aquatic plant toxicity testing is required for all herbicides. The requirement for this study is not tied to the level of risk to terrestrial plants. The terrestrial plants are vastly different than aquatic plants, especially algae and diatoms, and thus results for terrestrial plants cannot be used as an indicator of risk, or lack thereof, to aquatic plants.

3. *In the discussion of possible endocrine-disruption effects of diclofop-methyl, chronic toxicity effects were cited which did not reflect the results of chronic mammalian studies done with diclofop-methyl.*

In the discussing the possiblity of diclofop-methyl causing endocrine disruption, I had cited effects on reduction in size of seminal vesicles, ovaries, and uterine horns (LOEL=5120 ppm, 28-day rat feeding study) and interruption of spermatogenesis (LOEL=1250 ppm, 30-day dog feeding study). I had taken these results from a report that I generated from the OPP "Tox Oneliners" database. The results cited above were from studies listed on this report for "HOE 070542", which I mistaken as being diclofop-methyl, but is actually a completely unrelated chemical. One study that was with diclofop-methyl (MRID 097108) found increased resorption of fetuses at 32 mg/kg, but this result in itself is not convincing evidence to suggest endocrine disruption activity. Therefore, we agree with the registrant on this matter, and the text of the EFED chapter has been changed to state that the mammalian toxicity data does not provide

evidence that diclofop-methyl ccauses effects related to disruption of the endocrine system.

4. *Besides biodegradation, hydrolysis is a major contributor to the dissipation of diclofop-methyl.*

We agree that hydrolysis would be a major contributor to dissipation of diclofop-methyl when the pH is low (<7). The text on page 12 has been revised accordingly.

5. The water solubility is given as 3 mg/L, but the correct value is 0.8 mg/L.

The correct value for the water solubility of diclofop-methyl is 0.8. Corrections were made throughout the document.

6. *The EFED chapter erroneously stated results from a developmental toxicity study as a dietary dose, in units of ppm, when it was actually an oral dose, in units of mg/kg bodyweight. Furthermore, it is not appropriate to assess chronic risk from a study in which the toxicant was administered as an oral dose.*

Aventis is correct in that the results of the developmental toxicity study were erroneasly given in units of ppm when the correct units were mg/kg Bwt. It is standard procedure to use a conversion factor of 20 when estimating a dietary dose from an oral dose. Thus, the NOAEL and LOAEL of 10 and 32 mg/kg bodyweight, respectively, are equivalent to dieatry doses of 200 and 640 ppm, respectively. The table and discussion on page 24.

The risk assessment is now based on the results from the lowest ecologically relevant endpoint, which was increased pup mortality in the rat 3-generation study. The developmental study, in which the dose was administered by oral gavage, is no longer used as a basis for the chronic risk assessment. While dosing via oral gavage is less relevant to dietary exposure than is dietary dosing, a study with oral gavage can still provide useful information for ecological risk assessment. In this case, the developmental study indicates that reproductive impairment can occur from relatively short-term exposure to diclofop-methyl, although somewhat higher doses are required compared to studies with long-term exposure.

7. *In reporting the results for effects on seedling emergence, the most sensitive endpoint for ryegrass was given as "plant height". While this is true for the EC_{25} value, the most sensitive endpoint based on the NOAEL was radical length.*

The table was revised to indicate that plant height was the most sensitive endpoint for ryegrass was plant height when based on the EC_{25} and radicle length when based on the NOAEL.

8. *Typographical errors were noted on pages 10, 26, and 29.*

These typographical errors were corrected.